K062388

FEB 2 2 2007

510(k) Summary

DocuSys Inc. Anesthesia Information and digital-Drug Management System

The following information is in accordance with 21 CFR 807.92

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

DocuSys, Inc.
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Mobile Al.36609
Tel: 251-461-9903
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Contact Person: Gordon J. Peters, Director Regulatory Compliance
Cell (770)842-1489

Date Prepared: May15, 2006

Name of Device

Anesthesia Information and digital-Drug Management System, DocuSys, Inc.

Device Classification/Classification Panel

21 C.F.R. 868.5160 Class II
Anesthesiology Panel

Predicate Devices

1) PHILIPS COMPURECORD PERI-OPERATIVE INFORMATION SYSTEM (K030939)
2) SAFERsleep System (K050883)

INTENDED USE

The DocuSys Anesthesia Information and digital-Drug Management System offers anesthesia a comprehensive record keeping system with advanced patient safety features. The clinician begins interacting with the system through the electronic anesthesia pre-operative assessment in which patient data relative to anesthesia is recorded. Electronic documentation of the patient's allergies and home medications allows for proactive adverse drug event screening when the patient is in the operating room prior to anesthesia delivering drugs.

The DocuSafe electronic anesthesia information system allows the clinician to record anesthesia related events in the pre-op, intra-op, and PACU areas. The DocuSafe software receives physiologic data from various patient monitoring devices. Clinicians enter drug information onto the anesthesia record in one of two methods: a) manually selecting the drug from a list of drugs in the formulary, or b) through the use of DocuSys' optional digital-Drug Management System. If the optional d-DMS is used, the clinician may scan a barcode affixed

to a Syringe Label Cradle or use DocuJect to record the drug delivery. A Formulary Reference module, managed by pharmacy, contains drug specific information used for documenting drugs on the anesthesia record, performing ADE checks, and submitting medication utilization information for billing purposes.

The DocuRx pharmacy component of the digital-Drug Management System provides for pre-screening of medications that are ordered by anesthesia to check for any potential adverse drug events. It also provides a methodology for narcotics tracking through its comprehensive medication tracking and wasting feature.

Each component of the Anesthesia Information and digital-Drug Management System plays an integral part in standardizing medication administration techniques and documentation.

DESCRIPTION OF THE DEVICE/SUBSTANTIAL EQUIVALENCE

The DocuSys System is substantially equivalent to the Philips CompuRecord Peri-Operative Anesthesiology Information System, (K030939) and the SAFERsleep System (K050883) marketed by Safer Sleep, LLC.

All three systems are software application programs that run on Windows-based computer systems. The Phillips, Safer Sleep and DocuSys systems are intended for use by anesthesiologists for the tracking and record keeping of anesthesia procedures including the administration of drugs. All three systems can connect electronically to patient monitors that are used during the anesthesia procedure to provide a detailed record of the anesthesia process for record retention and billing purposes.

PERFORMANCE DATA

The Anesthesia Information and digital-Drug Management System uses currently available technology found in legally marketed devices. Testing was performed at two levels to ensure that the Anesthesia Information and digital-Drug Management System would perform as intended: Non-clinical bench testing to test each function and clinical testing to verify performance of the software. The Anesthesia Information and digital-Drug Management System meets applicable standards for performance and EMC compliance.

Non-clinical Testing

Testing was performed to evaluate the functional modules.

Clinical Testing

Clinical testing was performed by DocuSys and third party clinicians. All values were taken in a normal operating environment. The testing shows that the data was accurately received and recorded.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2007

Mr. Gordon J. Peters
Director Regulatory Compliance
DocuSys, Incorporated
820 S. University Boulevard, Suite 3-H
Mobile, Alabama 36609

Re: K062388
Trade/Device Name: The Anesthesia Information and Digital-Drug Management System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: February 9, 2007
Received: February 16, 2007

Dear Mr. Peters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) __K062388_____

Device Name: The Anesthesia Information and digital- Drug Management System

Indications for Use:

The DocuSys Anesthesia Information and digital-Drug Management System offers anesthesia a comprehensive record keeping system with advanced patient safety features. The clinician begins interacting with the system through the electronic anesthesia pre-operative assessment in which patient data relative to anesthesia is recorded. Electronic documentation of the patient's allergies and home medications allows for proactive adverse drug event screening when the patient is in the operating room prior to anesthesia delivering drugs.

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Each component of the Anesthesia Information and digital-Drug Management System plays an integral part in standardizing medication administration techniques and documentation.

Prescription Use __ X___ OR Over-The-Counter Use____

(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Linda May for M. Husband

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

K062388